4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the Federal Register of March 13, 2015. The amendment is being made to reflect a change in the April 30th Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring MD 20993-0002, patricio.garcia@fda.hhs.gov, 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), code EN. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 13, 2015 (80 FR 13392), FDA announced that a meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee would be held on April 30 and May 1, 2015. On page

13393, in the first and second columns, the Agenda portion of the document is changed to read as follows:

On April 30, 2015, the Agency is adding three Agenda items to the original five agenda items posted in the March 13, 2015, Federal Register document. The three additional items are: Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), and Nasal Septal Button Devices. The committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Insert)," Product Code EWD, as unclassified under the 510(k) premarket notification authority. Circumaural Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Circumaural)," Product Code EWE, as unclassified under the 510(k) premarket notification authority. Tactile Hearing Aid Devices are currently regulated under the heading, "Hearing Aid, Tactile," Product Code LRA, as unclassified under the 510(k) premarket notification authority. Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient) are currently regulated under the heading, "Aids, Speech Training For The Hearing Impaired (Battery-Operated or Non-Patient)," Product Code LFA, as unclassified under the 510(k) premarket notification authority. Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact) are currently regulated under the heading,

"Aids, Speech Training For The Hearing Impaired (AC-Powered and Patient-Contact)," Product Code LEZ, as unclassified under the 510(k) premarket notification authority. Vestibular Analysis Apparatuses are currently regulated under the heading, "Apparatus, Vestibular Analysis," Product Code LXV, as unclassified under the 510(k) premarket notification authority. Middle Ear Inflation Devices are currently regulated under the heading, "Device, Inflation, Middle Ear," Product Code MJV, as unclassified under the 510(k) premarket notification authority. Nasal Septal Button Devices are currently regulated under the heading, "Button, Nasal Septal," Product Code LFB, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the risks, safety and effectiveness, and the regulatory classification of Hearing Protectors, Circumaural Hearing Protectors, Tactile Hearing Aids, Speech Training Aids for the Hearing Impaired (Battery Powered or Non-Patient), Speech Training Aids for the Hearing Impaired (AC-Powered and Patient-Contact), Vestibular Analysis, Middle Ear Inflation Devices, and Nasal Septal Button Devices.

On May 1, 2015, the committee will discuss key issues related to a potential pre- to postmarket shift in clinical data requirements for modifications to cochlear implants in pediatric patients. These issues are categorized into three broad areas for discussion:

1. Cochlear implant changes (e.g. sound processing features, patient characteristics) that may be suitable for this pre- to postmarket shift in clinical data requirements.

2. Appropriate premarket clinical data requirements to support pre- to postmarket shift (e.g. leveraging clinical data from adults and/or older children.)

3. Clinical study design considerations (e.g. study endpoints and test metrics, subject characteristics) for postmarket studies to confirm safety and effectiveness and inform future labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 24, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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